# Sani-Cloth Plus Germicidal Disposable Cloth / Professional Disposables International (PDI) RECALL (8/14)

### Reason/Information:

Professional Disposables International issued a recall on the following materiel (See Image on Message under Additional Documentation/Attachment). Reason: Testing results raised a question about efficacy for Mycobacterium bovis BCG (tuberculosis). Pending further review and analysis, PDI is voluntarily removing that claim from the Sani-Cloth Plus.

While testing is still ongoing, initial results raised a question about efficacy for Mycobacterium bovis BCG (tuberculosis). Pending further review and analysis, PDI is voluntarily removing that claim form the Sani-Cloth Plus. The company is working to resolve this issue as soon as possible. The company is optimistic that the Mycobacterium bovis BCG (tuberculosis) claim will be back on the product label in the future.

PDI has taken this step voluntarily due to preliminary test results which indicate the product may not pass testing necessary to support a Mycobacterium bovis BCG (tuberculosis) claim. Sani-Cloth Plus continues to be efficacious for use against the remaining 16 microorganisms referenced on the label (See attached updated technical data bulletin). The removal of the Mycobacterium bovis BCG (tuberculosis) claim only applies to PDI Sani-Cloth Plus.

PDI is currently obtaining new labels and will begin shipping replacement product shortly. In the meantime, PDI offers several other products that have been proven efficacious for Mycobacterium bovis BCG (tuberculosis). These products are:

- ----Super Sani-Cloth Germicidal Disposable Cloths (EPA Reg. No. 9480-4)
- -----Item numbers: Q55172 and Q86984
- ----Sani-Cloth AF3 Germicidal Disposable Cloths (EPA Reg. No. 9480-9)
- -----Item numbers: P13872 and P63884
- ----Sani-Cloth Bleach Germicidal Disposable Cloths (EPA Reg. No. 9480-8)
- -----Item numbers: PS4072 and P25784

# **Disposition/Instructions:**

Return all existing inventory of the Sani-Cloth Plus to Nice Pak Products, ATTN: RMA, 1 Nice Pak Road (formerly Haworth Road, Jonesboro, Arkansas 72404.

Prior to returning the product, call PDI at 800-999-6423 to obtain a RMA number. The RMA number must be referenced on all paper work to ensure proper credit.

PDI will be sending end users who have received this product in the last 24 months a separate notification that the Mycobacterium bovis BCG (tuberculosis) claim is being removed from the

label until testing is completed. Customers can continue to use the Sani-Cloth Plus. The product continues to be efficacious for all other labeled claims.

For general questions call 804-723-7897, 804-723-7779, 804-723-7816 or 800-999-6423, between 8:45 a.m. and 5:15 p.m., EDT.

Item Information:

NSN (FSC-NIIN): 6515-NS1 Part Number: Q89072

Nomenclature: SANI-CLOTH PLUS GERMICIDAL DISPOSABLE CLOTH

UI: EA

Manufacturer: PROFESSIONAL DISPOSABLES INTERNATIONAL

Distributor: Owens & Minor

LOT / SN:

ALL

NOTES:

NOTE 1:

EPA Reg. No. 9480-6

NOTE 2:

O&M SKU #4725Q89072 NSN (FSC-NIIN): 6515-NS2 Part Number: Q85084

Nomenclature: SANI-CLOTH PLUS GERMICIDAL DISPOSABLE CLOTH

UI: EA

Manufacturer: PROFESSIONAL DISPOSABLES INTERNATIONAL

Distributor: Owens & Minor

LOT / SN:

ALL

NOTES:

NOTE 1:

EPA Reg. No. 9480-6

NOTE 2:

O&M SKU #4725Q85084

**POC Contact Information:** 

**USAMMC-E** 

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**US AIR FORCE** 

Email: <u>afmoa.sgalc@us.af.mil</u> Phone (COMM): 301-619-4170

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**US NAVY** 

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# Additional Message Recipients:

Please ensure widest dissemination of information to all interested entities.

# Message Dissemination Authorization:

### **US AIR FORCE**

AF Activities Will Take Action As Prescribed In Afi 41-209, Medical Logistics Support, Chapters 3 And 9. For MAJCOMS & NGB--This Msg Has Been Transmitted To All Designated Subordinate Medical Activities.

# **US ARMY**

See Army Regulation (Ar) 40-61, 28 January 2005, Chapter 4, And The Department Of The Army Supply Bulletin (Sb 8-75-11) For Applicable Policies And Procedures.

#### DOD

DODD 5105.22 and DODD 6025.13

Additional Documentation located <u>here</u>.